UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,185	02/25/2002	Thomas Dag Horn	023533-0144	4869

7590 12/26/2006

HUGH MCTAVISH
MCTAVISH PATENT FIRM
429 BIRCHWOOD COURTS
BIRCHWOOD, MN 55110

EXAMINER	
YU, MISOOK	
ART UNIT	PAPER NUMBER
1642	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
2 MONTHS	12/26/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/081,185
Filing Date: February 25, 2002
Appellant(s): HORN ET AL.

Hugh McTavish
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 10/10/2006 appealing from the Office action mailed 05-31-2005.

This revised Examiner's Answer is in response to the "ORDER RETURNING UNDOCKETED APPEAL TO EXAMINER" mailed on July 13 2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

Bellone et al., "Cancer immunotherapy: synthetic and natural peptides in the balance" Immunology Today, Vol20 (1999) PP.457-462

Gaiger et al., "Immunity to WT1 in the animal model and in patients with acute myeloid leukemia" Immunology, vol96 (August 2000) pp. 1480-1489

6033673	CLEMENTS	03-2000
2002/0009429 A1	BOSTWICK	01-2002

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

(a) Claims 1, 4-7, 33, 36, and 48-51 are rejected under 35 U.S.C. 102(e) as being anticipated by Bostwick, E. (US2002/0009429 A1, January 29, 1999).

Bostwick, E. teaches and claims (see page 8, column 2, under claims) a pharmaceutical composition comprising at least two antigens and a pharmaceutically acceptable carrier, wherein said antigens are selected from the group consisting of bacterial and *candida albicans* antigens wherein said composition does not contain an immunogenic additive other than said antigens, wherein one of said antigens is an allergenic *Candida albicans* extract. Although the reference does not characterize the pharmaceutical composition comprising the antigens as useful for treating an epithelial tumor or capable of inducing a cutaneous delayed-type hypersensitivity response, the

claimed pharmaceutical compositions appear to be identical as those disclosed in the prior art, absent evidence to the contrary.

WITHDRAWN REJECTIONS

The following ground of rejection is not presented for review on appeal because it has been withdrawn:

(b) The rejection of Claims 1, 4-7, 33, 36-37 and 48-51 under 35 U.S.C. 102(e) as being anticipated by Clements, J. (US Patent No. 6,033,673, March 18, 1998) is withdrawn in view of applicant's arguments and evidence thereof.

(c) Claims 1, 4-7, 15, 33, 36-37, and 48-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bostwick, E. (US2002/0009429 A1, January 29, 1999) in further view of the CANDIN® package insert text, IDS, Reference A12, submitted March 14, 2003.

Bostwick teaches as set forth above with regards to claims 1, 4-7, 33, 36, and 48-51.

Bostwick does not specifically teach a kit comprising a hypodermic needle or a high pressure injection device comprising the pharmaceutical composition of Claim 1

(Claim 15) or wherein the *Candida albicans* extract for intradermal testing is the *Candida albicans* Skin Test Antigen (Claim 37).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to include kits comprising injections devices such as hypodermic needles comprising the pharmaceutical compositions as taught Bostwick because the reference teaches the desirability of presenting the agents for pharmaceutical purposes that can be administered intramuscularly or subcutaneously (column 9, line 48) Hence, it would be obvious to anyone of ordinary skill to include an injection device comprising the pharmaceutical antigens for the purposes of inoculation. Further, kits provide for increased marketability, convenience, reliability, and economy. Further, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to include the *Candida albicans* Skin Test Antigen because the reference suggests and encourages the use of *Candida albicans* antigens in their pharmaceutical compositions. According to the CANDIN® package insert, the Skin Test Antigen is readily available and easily assessable. Thus, one would be motivated to purchase the *Candida albicans* because it is readily available in packaged form.

(10) Response to Arguments

Issue (a)

Appellants do *not* argue whether or not claims 1, 4-7, 33, 36, and 48-51 are anticipated by Bostwick E. (US2002/0009429 A1), but rather that the Declaration filed under 37 CFR 1.131 (11/19/2004) by Inventor Horn established conception of the claimed invention prior to the filing date of the Bostwick application.

As set forth previously, the Declaration by Dr. Horn only established conception of a pharmaceutical composition comprising the mumps and candida antigen, not the claimed composition of "bacterial" and candida antigen. Further, the Declaration was accompanied by an approval letter signed by Dr. Faas, M.D. entitled, "Application of Mumps and Candida Intradermal Skin Tests in Patients With Verruca Vulgaris". This letter does not provide evidence that "bacterial" antigens were included. Despite the latter, appellant's argue that the exclusion of a bacterial antigen in the pharmaceutical composition is irrelevant because Dr. Horn "believed" (Declaration, page 2) that any antigen that induced a cutaneous DTH response would successfully treat warts and other benign epithelial tumors. This argument has been carefully considered but is not found persuasive because the affidavit does not contain facts showing a completion of the invention that is commensurate with the extent of the invention claimed. The 37 CFR 1.131 affidavit or declaration must establish possession of either the whole invention claimed or something falling within the claim (such as a species of a claimed genus), in the sense that the claim as a whole reads on it. *In re Tanczyn*, 347 F.2d 830, 146 USPQ 298 (CCPA 1965).

However, Appellants argue (Brief, pages 6-7) that the facts in this case show parallels to those of *In re Stryker*, 435 F.2d 1340 (CCPA 1971) in which the CCPA overturned the BPA with regards to the Board's application of *Tanczyn*. This argument has been considered but is not found persuasive, as the facts in this case do not parallel the decision made by the CCPA regarding *In re Stryker*. The CCPA overruled the Board because the Board inappropriately applied the ruling of *In re Tanczyn*. In this case, it is believed that *Tanczyn* is applicable because Dr. Horn's Declaration failed to demonstrate facts showing a completion of the invention commensurate with the extent of the invention claimed, i.e. Dr. Horn's declaration did not provide evidence of possession of the claimed bacterial and candida antigens. In contrast, Strkyer's declaration professed to have met the weight percentages, but contained no "corroborating evidence" showing those weight percentage limitations. The CCPA held that an antedating affidavit is sufficient where it alleges conception and reduction to practice of a claimed process even when there is no corroborating evidence showing specific limitations. In contrast, the dispute here does not involve a specific process nor any specific limitations or percentages or ranges. Rather the claims are drawn to a pharmaceutical composition comprising two distinct antigens from different organisms for which applicant has neither shown possession of nor reduction to practice.

Appellants further argue that the Declaration establishes possession of the "originally" filed claims. For example, originally filed Claim 1 was drawn to a pharmaceutical composition comprising at least two antigens. Appellants argue that the broader filed original claim would enjoy the embodiments shown by Dr. Horn's

declaration, and it "cannot be law" that the Examiner can demand that the claims be narrowed to make searching easier, and then assert that the Appellant's showing of possession with a Rule 131 Declaration is not sufficient with the narrow claims. This argument has been considered but is not found persuasive. On the contrary, the examiner is allowed by law to restrict the inventions into patentably distinct groups. Under the statute an application may properly be restricted when the inventions have been shown to be independent or distinct and when there exists a serious burden on the examiner. It is noted that the originally filed claims were properly restricted (Action mailed 04-09-2004) and said restriction was made final (Action mailed 07-26-2004). Thus, the assertion that Dr. Horn's Declaration would have been sufficient to remove the prior art with respect to the original claims intact appears irrelevant.

Alternatively, the Brief argues (bottom of page 7 through page 8) that evidence of a reduction to practice of the unclaimed mumps and candida antigen establishes possession of the claimed "bacterial and candida antigens" because "the latter composition is obvious in view of the former". Appellants refer to the decision held in *in Re Spiller* in which the CCPA held that appellant has shown a reduction to practice of his basic invention, which showing will also suffice as to claims differing therefrom only in details which are obvious to one of ordinary skill in the art. Appellants argue that it would have been obvious to one of ordinary skill in the art, in view of their invention of using mumps antigen and candida antigen to treat warts, that any antigen which induces or is capable of inducing a delayed type hypersensitivity response could be used to treat warts. These arguments have been carefully considered but are not found

persuasive because it would appear that the obviousness only applies to possession when the claimed invention carries with it certain readily known variations and adaptations. In this case, there is insufficient evidence to suggest that every antigen in the world that induces a cutaneous delayed type hypersensitivity would predictably substitute for the mumps and candida antigens.

Issue (b)

This issue is moot since the rejection was withdrawn.

Issue (c)

Appellants argue that Bostwick should be removed as a reference because of their arguments under Issue (a) above. Appellants remaining arguments only concern the prior art of Clements, which was withdrawn as a reference.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Misook Yu, Ph.D.

Conferees:

Jeffrey Siew, J.D.

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER

Larry Helms, Ph.D.

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER